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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,621	03/10/2004	Edward I. Wulfman	89000.3010NP	6171
20601	7590	09/14/2006	EXAMINER	
SPECKMAN LAW GROUP PLLC 1201 THIRD AVENUE, SUITE 330 SEATTLE, WA 98101				SMITH, PAUL B
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,621	WULFMAN ET AL.	
	Examiner	Art Unit	
	Paul B. Smith	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 March 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 10 March 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/2/2005</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 9/2/2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner considers the references cited therein.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 5, 9, 12, 16-22, and 24-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Wulfman *et al.* ('190).

4. Wulfman *et al.* discloses an intraluminal material removal system comprising a catheter (40), a sealed lumen (46), ports (75), a drive assembly (24), a drive shaft (25), an operating head (50), and control pod (14). (See Figure 5-6)

5. As to claim 2, the drive assembly comprises a direct current variable speed micro-motor. (See Paragraph 75 Line 11-12)

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6. As to claim 5, the control unit incorporates selectable operator features such as desired rotation rate and/or rotation profile for the cutter assembly; desired advance rate and/or advance profile for the cutter assembly; desired aspiration rate and/or profile; desired infusion rate and/or profile; and the like. (See Paragraph 75 Line 19-22 and Paragraph 150)

7. As to claim 9, an aspiration source is provided consisting of a vacuum pump. (See Paragraph 70)

8. As to claim 12, the control pod incorporates a fluid seal assembly (618) to prevent ingress of gas to the catheter system. (See Figure 5)

9. As to claim 16, it is inherent that the system would be provided as a sterile kit prior to operation. Further, the system would be capable of being disposed post operation.

10. As to claim 17, it is inherent that the system would comprise a fluid receptacle in fluid communication with the catheter system for infusion and aspiration.

11. As to claim 18, the drive motor is coupled to a sliding actuator mounted on the catheter system. (See Figure 2)

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12. As to claim 19-21, a guidewire brake system (22) is incorporated with control pod (14). (See Figure 2) The brake system selectively prevents actuation of the drive system. (See Paragraph 78)

13. As to claim 22, a slip seal adaptor is mounted on the catheter system. (See Paragraph 67)

14. As to claim 24-25 and 27-28, the system further comprises a console unit (12) is consisting system controls, display, and a vacuum motor. The console unit is in electrical communication with the control pod. (See Figure 1)

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wulfman *et al* ('190) in view of Fine *et al.* ('509).

18. Wulfman *et al.* discloses an intraluminal material removal system comprising a catheter (40), a sealed lumen (46), ports (75), a drive assembly (24), a drive shaft (25), an operating head (50), and control pod (14). (See Figure 5-6) The drive assembly comprises a direct current variable speed micro-motor. (See Paragraph 75 Line 11-12)

19. Wulfman *et al.* fails to disclose a current that is adjusted under load conditions to maintain any specified rotational output.

20. Fine *et al.* teaches adjusting the rotational speed based on the load requirements by altering the current and voltage of the motor. (See Column 16 Lines 36-45)

21. It would have been obvious to one of ordinary skill in the art to modify the disclosure of Wulfman *et al.* with the teaching of Fine *et al.* to provide a system with a drive motor that is adjusted dynamically to load conditions.

22. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wulfman *et al.* ('190) in view of Barditch *et al.* ('425).

23. Wulfman *et al.* discloses an intraluminal material removal system comprising a catheter (40), a sealed lumen (46), ports (75), a drive assembly (24), a drive shaft (25), an operating head (50), and control pod (14). (See Figure 5-6)

24. Wulfman *et al.* fails to disclose a cascaded variable regulator voltage source.

25. Barditch *et al.* teaches a cascaded power supply for producing a clean dc output.

26. It would have been obvious to one of ordinary skill in the art to modify the disclosure of Wulfman *et al.* with the teachings of Barditch *et al.* to provide a power source that corrects the output voltage based on load conditions.

27. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wulfman *et al.* ('190) in view of Grinberg *et al.* ('956).

28. Wulfman *et al.* discloses an intraluminal material removal system comprising a catheter (40), a sealed lumen (46), ports (75), a drive assembly (24), a drive shaft (25), an operating head (50), and control pod (14). (See Figure 5-6)

29. Wulfman *et al.* fails to disclose a torque selection feature.

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30. Grinberg *et al.* teaches a control unit for controlling the operations of a motor such as speed, torque, and direction of rotation. Further the control unit prevents damage by limiting the torsion applied by the motor. (See Column 7 Lines 49-62)

31. It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Wulman *et al.* with the teachings of Grinberg *et al.* to provide torque control for the motor to prevent damage to the patient and device.

32. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wulfman *et al.* ('190) in view of Valley *et al.* ('325).

33. Wulfman *et al.* discloses an intraluminal material removal system comprising a catheter (40), a sealed lumen (46), ports (75), a drive assembly (24), a drive shaft (25), an operating head (50), and control pod (14). (See Figure 5-6)

34. Wulfman *et al.* fails to disclose a sealed catheter with coil to reinforce and prevent the catheter from kinking.

35. Valley *et al.* teaches a tube may be reinforced with wire or filament braiding or coils for increased stiffness, torque control or kink resistance. (See Column 22 Lines 50-53)

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36. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Wulfman *et al.* with the teachings of Valley *et al.* to provide a sealed catheter that is kink-free.

37. Claims 10 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wulfman *et al.* ('190) in view of Ross *et al.* ('111).

38. Wulfman *et al.* discloses an intraluminal material removal system comprising a catheter (40), a sealed lumen (46), ports (75), a drive assembly (24), a drive shaft (25), an operating head (50), and control pod (14). (See Figure 5-6)

39. Wulfman *et al.* fails to disclose an aspiration system comprising a plurality of vacuum pumps.

40. Ross *et al.* teaches a surgical cutting system with an aspiration system comprising a plurality of vacuum pumps. (See Figure 13)

41. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Wulfman *et al.* with the teachings of Ross *et al.* to provide an aspiration system with multiple vacuum pumps.

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42. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wulfman *et al.* ('190) in view of Nash *et al.* ('170).

43. Wulfman *et al.* discloses an intraluminal material removal system comprising a catheter (40), a sealed lumen (46), ports (75), a drive assembly (24), a drive shaft (25), an operating head (50), and control pod (14). (See Figure 5-6)

44. Wulfman *et al.* fails to disclose a coupling means between drive shaft and drive motor comprising ball bearings and sliding tubes.

45. Nash *et al.* teaches a drive assembly comprising a drive shaft connects to a drive motor through a ball bearing assembly. Where the ball bearing assembly (350) comprising an outer tubes with the drive shaft slidably held within the outer tube by balls. (See Figure 13)

46. It would have been obvious at the time of the invention to modify the disclosure of Wulfman *et al.* with the teachings of Nash *et al.* to provide a drive assembly comprising two tubes in sliding arrangement held in place by ball bearings.

47. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wulfman *et al.* ('190) in view of Plassche, Jr. *et al.* ('576).

48. Wulfman *et al.* discloses an intraluminal material removal system comprising a catheter (40), a sealed lumen (46), ports (75), a drive assembly (24), a drive shaft (25), an operating head (50), and control pod (14). (See Figure 5-6)

49. Wulfman *et al.* fails to disclose a control pod that incorporates a speed adjustment switch, an adjustable head with at least two operating conditions and a switch allowing selection between operating head diameter.

50. Plassche, Jr. *et al.* teach a surgery system comprising an operable head with two operational conditions. (See Figure 1A and 1B) The speed and diameter of the operable head is control via switches in a control pod (100). (See Figure 2)

51. It would have been obvious to one of ordinary skill in the art to modify the disclosure of Wulfman *et al.* with the teachings Plassche, Jr. *et al.* to provide a control pod with switches controlling the speed and diameter of the operable head.

52. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wulfman *et al.* ('190) in view of Belef *et al.* ('755).

53. Wulfman *et al.* discloses an intraluminal material removal system comprising a catheter (40), a sealed lumen (46), ports (75), a drive assembly (24), a drive shaft (25), an operating head (50), and control pod (14). (See Figure 5-6)

54. Wulfman *et al.* fails to disclose an extendable, telescoping guidewire support mounted in the control pod.

55. Belef *et al.* teaches an extendable, telescoping guidewire support (51) mounted on a drive sled (26). (See Figure 1)

56. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Wulfman *et al.* with the teachings of Belef *et al.* to provide a telescoping guidewire support.

Conclusion

57. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Smith whose telephone number is 571-272-6022. The examiner can normally be reached on 8 am - 4 pm.

58. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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59. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul B Smith
Examiner
Art Unit 3763

PBS
September 8, 2006



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